TAVI: who, when and how?

A few comments

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Key question:
Which patients require which treatment?
Reasons to refuse treatment

- Too old or too sick
- Procedure too risky
- Very limited life expectancy
- Patient does not want treatment
Reasons to refuse treatment

- STS > 15-20
- PHT with right heart failure
- Long term O2 dependence (smoking)
- Chronic renal disease ± dialysis
- Liber disease with MELD > 15
- Dementia, psychologically „given up“
- Extreme frailty, wheel chair bound
Reasons to refuse treatment

- Inoperable
  - AVR
  - TAVR only in trials
- Low or Moderate Utility
- High Utility: TAVR or AVR
- Reasonable Surgical Risk: 8-15%
- Irrational, reckless, financially irresponsible
- Surgical Risk > 15%

Also consider: Age, co-morbidities, life expectancy, higher CVA/TIA risk with TAVR (3x in P-1A “AT” TF stratum), adverse consequences of AR (PPL), unknown valve durability.
Reimbursements

„Payers (HMO, insurances etc.) may have an interest in limiting reimbursement of high risk devices only to those indications for which there is a high level of evidence of efficacy and cost effectiveness“ 18

Treatment of high-risk and inoperable patients is „saturated“

Isolated Aortic Valve Replacement in Germany
Guidelines are not laws
...and will be adapted!

### Table 11: Recommendations for the use of transcatheter aortic valve implantation

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
<th>Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVI should only be undertaken with a multidisciplinary “heart team” including cardiologists and cardiac surgeons and other specialists if necessary.</td>
<td>I</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>TAVI should only be performed in hospitals with cardiac surgery on-site.</td>
<td>I</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td><strong>TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a “heart team” and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities.</strong></td>
<td>I</td>
<td>B</td>
<td>99</td>
</tr>
<tr>
<td>TAVI should be considered in high-risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a “heart team” based on the individual risk profile and anatomic suitability.</td>
<td>Iia</td>
<td>B</td>
<td>97</td>
</tr>
</tbody>
</table>
Large discrepancies in health care provision.

Swiss TAVI Registry 7/2014-6/2015

Minimal requirements
Guidelines are not laws
...and will be adapted!

Facts to be thought about before expanding TAVI to younger and low-risk patients
Guidelines and patients’ preferences

Of course TAVI is attractive for the patients since opening of the chest can be avoided. Patient’s preference relies principally on this advantage and on the potentially shorter duration of hospital stay while the need for permanent pacemaker, the significance of residual paravalvular leakage and the still unknown long-term term durability are usually not questionned by the patients.
Incidence, Timing, and Predictors of Valve Hemodynamic Deterioration After Transcatheter Aortic Valve Replacement

Del Trigo M, JACC 2016;67:644

Central Illustration: VHD After TAVR: Progression and Predictors

Progression of Transvalvular Mean Gradients Following TAVR
Results of the multivariate analysis show factors associated with a higher risk of transcatheter valve hemodynamic deterioration (VHD) after transcatheter aortic valve replacement (TAVR). BMI = body mass index; CI = confidence interval; HR = hazard ratio.

Del Trigo M, JACC 2016;67:644
Suradi HS, Hijazi ZM. TAVR update: Contemporary data from the UK TAVI and US TVT registries, Global Cardiology Science and Practice 2015:21 http://dx.doi.org/10.5339
New techniques - new problems

About inoperability!
Durchgeführte Therapie

**09.12.2015:** Einlage provisorischer Schrittmacher inguinal rechts

**15.12.2015:**

1. Carotis-Endarterektomie rechts
2. Patchrekonstruktion des aorto-mitralen Übergangs bei Abszessbildung
4. Biologischer Aortenklappenersatz mit 23 mm gestenteter Klappenprothese (Perimount Magna Ease Aortic, Edwards Lifesciences, SN 4619500, Lot S-15J3696, Model 3300TFX)
5. 1fach ACB mit Vene auf Marginalast

**28.12.2015:** Implantation 1-Kammer Schrittmacher (SJM Endurity MRI), VVIR 60-130/min
Transcatheter aortic valve implantation (TAVI): risky and costly

Many of the 40,000 transcatheter procedures so far carried out cannot be justified on medical or cost effectiveness grounds. Hans Van Brabandt, Mattias Neyt, and Frank Hulstaert examine why practice has gone beyond the evidence

Hans Van Brabandt researcher\textsuperscript{12}, Mattias Neyt researcher\textsuperscript{9}, Frank Hulstaert researcher\textsuperscript{19}
Statement - *Hans Van Brabandt* ¹

„Many of the 40,000 transcatheter procedures so far carried out cannot be justified on medical or cost effectiveness grounds.“

United States: growing demand from patients who are suitable for conventional surgery but who prefer the quicker and less painful transcatheter option.

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In April 2012, a New York securities analyst for the financial services company Wells Fargo estimated* TAVI could generate > $2.4bn (£1.5bn; €2bn) in sales in the US

– > 30% of aortic valve replacements by 2015.

Where and How?
Actual problems of „high-tech“ medicine

- High-Tech Medizin over-proportionally consumes financial ressources (equity)
- Paradigma: the most expensive treatment is performed in those patients with the shortest life expectancy!
- Success of an institution is largely dependent from economical factors
Actual problems of „high-tech“ medicine

- How to select „good“ cases for TAVI
- Who does inform the patient?
Surgical History
1. Aortic root replacement AADA 2002
2. Bio-Conduit replacement for Endocarditis 2005

Medical History
Dialysis for chronic renal failure stage V
Sever polycystic disease with Hepato-spleno-megalie

Actual problem
TTE 2015: severe aortic regurgitation, mild mitral regurg, LVEF 40%
Trans Carotid Corevalve 29mm Implantation
Trans Carotid Corevalve 29mm Implantation
Surgical History
Renal transplantation 1989
Repeat renal transplantation 1998
CABG 2005 (saphenous vein graft – RCA) for giant aneurysm RCA
Multiple peripheral artery with surgeries 2005/2006
PCI/STENT mid LAD 2010
ICD Implantation 2010 for out of hospital resuscitation

Medical History
Progressive aortic stenosis
Peripheral artery disease Fontain IV
Chronic renal failure (Glomerulopathy)

History of Present Illness
Dyspnea on exertion NYHA III, Severe aortic stenosis
TTE: (mean gradient 42mmHg, AVA 0.9cm2, LVEF 40%)
Current decision making and short-term outcome in patients with degenerative aortic stenosis: the Pooled-Rotterdam-Milano-Toulouse In Collaboration Aortic Stenosis survey

Nicolas M. Van Mieghem1*, MD, PhD; Nicolas Dumonteil2, MD; Alaide Chieffo3, MD; Yann Roux4, MD; Robert M.A. van der Boon1, MD, PhD; Gennaro Giustino3, MD; Eline Hartman1, MSc; Yaar Aga1, MSc; Louis de Jong1, MSc; Moussa Abi Ghanem2, MD; Bertrand Marcheix2, MD, PhD; Caterina Cavazza4, MD; Didier Carrié2, MD, PhD; Antonio Colombo3, MD, PhD; Arie-Pieter Kappetein1, MD, PhD; Peter P.T. de Jaegere1, MD, PhD; Didier Tchetché4, MD

1. Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands; 2. Hôpital Rangueil, Toulouse, France; 3. San Raffaele Scientific Institute, Milan, Italy; 4. Clinique Pasteur, Toulouse, France

EuroIntervention 2016:11: e1305
467 patients included in the eCRF

433 eligible patients

34 patients with formal exclusion criteria

43 patients with essential data missing

24 medical therapy

166 TAVI

200 SAVR
<table>
<thead>
<tr>
<th>Event</th>
<th>Overall</th>
<th>OMT</th>
<th>TAVI</th>
<th>SAVR</th>
<th>p-value</th>
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<tr>
<td>30-day mortality</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>All-cause (%)</td>
<td>11/390</td>
<td>0/24</td>
<td>10/166</td>
<td>1/200</td>
<td>0.004</td>
</tr>
<tr>
<td>Cardiovascular (%)</td>
<td>9/390</td>
<td>0/24</td>
<td>8/166</td>
<td>1/200</td>
<td>0.017</td>
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<td>Major stroke</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Non-disabling (%)</td>
<td>2/386</td>
<td>0/24</td>
<td>2/166</td>
<td>0/196</td>
<td>0.48</td>
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<tr>
<td>Disabling (%)</td>
<td>6/386</td>
<td>1/24</td>
<td>3/166</td>
<td>2/196</td>
<td></td>
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<tr>
<td>Transient ischaemic attack (%)</td>
<td>4/383</td>
<td>0/24</td>
<td>1/165</td>
<td>3/194</td>
<td>0.60</td>
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<td>Life-threatening bleeding (%)</td>
<td>18/386</td>
<td>0/24</td>
<td>4/165</td>
<td>14/197</td>
<td>0.05</td>
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<td>Major vascular complication (%)</td>
<td>10/381</td>
<td>0/23</td>
<td>8/165</td>
<td>2/193</td>
<td>0.06</td>
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<td>Acute kidney injury</td>
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<td></td>
<td></td>
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<tr>
<td>None (%)</td>
<td>339/388</td>
<td>22/24</td>
<td>153/166</td>
<td>164/198</td>
<td>0.26</td>
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<td>Stage 1 (%)</td>
<td>28/388</td>
<td>1/24</td>
<td>6/166</td>
<td>21/198</td>
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<td>Stage 2 (%)</td>
<td>9/388</td>
<td>0/24</td>
<td>3/166</td>
<td>6/198</td>
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<td>Stage 3 (%)</td>
<td>8/388</td>
<td>1/24</td>
<td>3/166</td>
<td>4/198</td>
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<td>Dialysis required (%)</td>
<td>5/386</td>
<td>0/23</td>
<td>2/166</td>
<td>3/197</td>
<td>0.68</td>
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<td>Permanent pacemaker requirement (%)</td>
<td>34/386</td>
<td>0/23</td>
<td>27/166</td>
<td>7/197</td>
<td>&lt;0.001</td>
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<td>New left bundle branch block (%)</td>
<td>23/386</td>
<td>0/24</td>
<td>19/164</td>
<td>4/198</td>
<td>0.004</td>
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<tr>
<td>New-onset atrial fibrillation (%)</td>
<td>71/386</td>
<td>0/24</td>
<td>7/166</td>
<td>64/196</td>
<td>&lt;0.001</td>
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<tr>
<td>Paravalvular aortic regurgitation (%)</td>
<td>&lt;moderate 323/360 (75.8)</td>
<td>146/149 (98)</td>
<td>14/187 (7.5)</td>
<td>&lt;0.001</td>
<td></td>
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<tr>
<td>Moderate-severe (%)</td>
<td>1/360</td>
<td>0/3</td>
<td>1/149</td>
<td>0/187</td>
<td></td>
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<tr>
<td>Length of stay (days, med [IQR])</td>
<td>9.0 (7.0-11.0)</td>
<td>3.0 (1.0-5.0)</td>
<td>8.0 (6.3-10.0)</td>
<td>9.0 (8.0-12.0)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
TAVI 2016

- Who: invasive cardiologist and surgeon
- When: inoperable / high-risk SAVR
- How: individualized approach in HR